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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,455	10/24/2005	Kozo Takeda	TAKEDA19	2196

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1652	
MAIL DATE	**DELIVERY MODE**
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,455	TAKEDA ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *8 and 11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9-10 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election of Invention of Group I, **Claims 1-20** (applicants are correct in assuming that **claim 20** is placed in Group I), and the further election of "DNA contaminants" and "antibody" in response to the restriction requirement mailed July 31, 2007 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore the requirement is still deemed proper and is made FINAL.

Status of the claims

Claims 1-22 are pending. **Claims 8 and 11-16** are withdrawn for pertaining to nonelected subject matter. **Claims 1-7, 9-10 and 17-20** are presently under examination.

Priority

The current application filed on October 24, 2005 claims is a 371 of PCT/JP03/11642 filed on 09/11/2003, which in turn claims priority to foreign application, JAPAN 2002-265609 filed on 09/11/2002. A certified copy of foreign document JAPAN 2002-265609 has been provided.

Information Disclosure Statement

The IDS filed August 28, 2006; May 23, 2007 and July 9, 2007 have been received and are signed and considered, a copy of the PTO 1449 is attached to the following document.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claims 2-3** applicants have defined "low conductivity" in variety of manners, which have created confusion. For example in **claim 2** the applicants have stated that the conductivity of the solution is between 0 to 100 mM expressed in molarity. This is not the conductivity of the solution but rather the concentration of the solution, also "mM" is a unit of molarity; therefore is redundant to indicate that the measurement is a measurement of molarity.

In **claim 3** applicants' have stated the ionic strength of the solution is between 0-2 but have not provided any units of measure. **Ionic Strength** is a measure of the total effect of all the ions in a solution. It is the sum of the molar concentration multiplied by the square of the valency of all the ions. The Ionic Strength (I) can be calculated from $I = 0.5 \times \text{Sum} (ci \times Zi^2)$ Where c is the concentration in Moles.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6, 7 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Faupel et al., United States Patent No. 4,971,670.

Faupel et al. teach an isoelectric focusing electrophoretic process for the separation and purification of an amphoteric or neutral chemical compound from one or more electrically charged chemical compound(s). The mixture to be separated is present within a hydraulic flow in chamber 8. Cylinders 5 and 12 contain immobilized pH-gradients or are replaced by amphoteric isoelectric pH-membranes. Each of said pH-gradients and pH-membranes has conductivity and both buffering and titrant capacity in its pH-interval. The extremities of said graidents or pH-membranes forming the ceiling and the floor of chamber 8 have **isoelectric points equal to** or just higher and just **lower than the isoelectric point of the protein of interest** which is kept at its ioselectric point in the hydraulic flow and does not enter said pH-gradients and pH-membranes. The described process has the advantage that the desired compound need not be detected and extracted from any matrix, e.g. from said pH-gradients, and that the recovery and purity of the desired compound is higher (Abstract; column 2, lines 40-67; column 9, lines 19-48).

Faupel et al. teach further that The amphoteric or neutral compound, kept in an isoelectric or uncharged state, is a chemical compound having no electrical net charge or being neutral under the conditions of the purification process and at the time when the separation from the undesired accompanying chemical compound(s) actually takes place. It is preferably a protein, enzyme or smaller peptide having at least two amino

acids or a compound containing a peptide- or protein moiety, e.g. a glycoprotein, but also a nucleic acid, complex lipid or complex carbohydrate (column 3, lines 10).

Faupel et al also teach that Preferably, the pH-gradients and pH-membranes are cast somewhere within a pH-range from about 3 to about 10, depending on the Immobilines and Ampholines available. If the compound of interest is amphoteric, the pH-values in the two gel extremities facing the flow chamber 8 have to be set just above and below or equal to the isoelectric point of said amphoteric substance with the precision required to keep it in the isoelectric state all the time (column 5, lines 1-9)

Thus Faupel et al. teach all the elements of **claims 1-2, 6, 7 and 17-18** and these claims are anticipated under 35 USC 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel et al., United States Patent No. 4,971,670 in view of EP 0313343.

Faupel et al. teach a method of purification as mentioned above.

Faupel et al. do specifically indicate that the solution has a morality between 0-100 mM; that the conductivity of the aqueous solution is between 0-300 mS/m or that the aqueous solution is selected from HCl, citric acid or acetic acid.

EP 0313343 teaches a method of purification wherein the solution has a morality between 0-100 mM (column 7, line 4); that the conductivity of the aqueous solution is between 0-300 mS/m (column 7, lines 2-3) and that the aqueous solution is acetic acid (column 7, line 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the purification conditions for the advantages of selective purification of the desired product as taught by Faupel et al. and EP 0313343, see EP 0313343 et al. at column 2, lines 1-15.

Claims 1, 9-10 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel et al., United States Patent No. 4,971,670 in view Vedantham et al. US Patent Publication No. 2003/0166869.

Faupel et al. teach a method of purification as mentioned above.

Faupel et al. do specifically that the DNA contaminates are removed; that the product to be purified is an antibody or that protein a (affinity chromatography) is used in the method of the invention.

Vedantham et al. teach that DNA contaminates are removed (page 2, paragraph 0024 and page 8 paragraph 0064); that the product to be purified is an antibody and that protein a (affinity chromatography) is used in the method of the invention (page 1, paragraph 0007 through paragraph 0008; page 2, paragraph 0020; page 4, paragraph 0041; page 8, Example pargrpah 0069 through page 7 paragraph 0070)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the purification conditions by using affinity chromatography for the because affinity chromatography is a well known and effect method of purifying antibodies as taught by Faupel et al. and Vedantham et al., see Vedantham et al. at column Page 1, paragraph 0003).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
Art Unit 1652

Robert B. M
9-25-2007

RBM